

## **REMARKS**

Amendments to the claims have been made to respond to the issues and concerns raised in the Office Action, to clarify aspects in the specification and claims, and to refine claim language. The amendments are believed to be consistent with the disclosure originally filed. The amendments also have been particularly presented to avoid, where applicable, any admission or estoppel, generally, negatively affecting the scope of protection provided by the disclosure and claims of the present application, and also in a manner that avoids prosecution history estoppel, limitation of the scope of equivalences, or the like. Any amendment should not be construed as an admission regarding the propriety of any objection or rejection raised in any Office Action, and the Applicant reserves the right to pursue the full scope of the unamended claims in any subsequent patent application as may be appropriate.

Claim 28 has been amended. Claims 1-27, 29, 32, 41-44, and 47-48 have been cancelled. Claims 28, 30-31, 33-40, 45-46, and 49-50 remain in the application. Each amendment is believed to have been made in accordance with Rule 121. However, should any unintended informality exist, it is requested that the undersigned be contacted by telephone so that it may be resolved as expediently as possible. It is believed the amendments fully respond to the issues raised in the Office Action. Further detail with respect to specific points raised in the Office Action is offered below.

Included with this response is an Information Disclosure Statement. While the Information Disclosure Statement includes additional information for the Office to consider and may increase the examination burden associated with this Application, the Applicant believes the Information Disclosure Statement is the only way for it to comply with its obligations under Rule 56.

The Office maintains concerns regarding the priority cases for this application. In the prior response, the Applicant provided page number and paragraph references to US 60/211,093, filed June 12, 2000, to which the current case claims priority. In reviewing

its files, the Applicant believes the Office may have a differently formatted copy of this case than applicant has in its possession, thereby perhaps causing the page number and paragraph citations in Applicant's previous response to not correctly track with the Office's copy of the priority case. The Applicant sincerely regrets this error, and provides revised page number and paragraph citations as follows, along with a copy of the priority case as filed attached to this response as Exhibit "A":

Aspects relating to managing a plurality of female bovine mammals for a reproductive factor may be found, *inter alia*, at page 1, first full paragraph ("By early weaning calves from spring calving cows, the dams have the ability to increase BCS prior to winter and decrease cost of feed without detrimental effects on calf performance"); page 2, second full paragraph ("Sexed semen is a relatively new technology that grants the IS ability to perpetuate the program using the female progeny of the initial heifers", "...AI using low dose sexed semen resulted in pregnancy rates in heifers that were 70-90% of unsexed traditional dose controls"); page 3, second full paragraph ("Behavior and physiological indicators monitored puberty..."); page 3, third full paragraph ("Estrus synchronization of the EW heifers was accomplished...", "Heifers were AI'd following standing heat up to 72 hr...", "... fixed-time mating of all remaining pubertal heifers occurred", "A 45 d breeding period allowed heifers three opportunities to be AI"); page 3 fourth full paragraph ("The IS produces all female progeny to perpetuate the system in subsequent years by utilizing sexed semen..."); page 4, second full paragraph ("...gains are attributed to adjusted feed rations to allow for gains that would induce early puberty", "Once the heifers began to cycle, the ration was backed down to avoid over-fattening of heifers and possible negative impacts on subsequent reproduction/calving difficulty"); page 4, third full paragraph ("This induction of early puberty is contributed to nutrition allowing greater gain and weight of the EW heifers", "At time of PGF injection..."); page 5, first full paragraph ("Heifers that became impregnated to sexed semen..."); page 5, second full paragraph ("...accomplished satisfactory gain performance of heifers which enabled induction of early puberty and resulted in 9 mo old heifers impregnated to sexed semen", "the opportunity for three services of AI may result in adequate overall pregnancy rate"), page 8 ("...the IS may include early weaning, estrous synchronization, and AI", "Sexed semen can be utilized to yield female progeny", "...induce early puberty by 9 mo of age", "...greater gains and weights of heifers induced early puberty...", "...resulted in 9 mo old heifers pregnant to sexed semen").

Aspects relating to inducing early puberty in said plurality of female bovine mammals may be found, *inter alia*, at page 2, first full paragraph ("... faster gains resulting in younger puberty age", "Early puberty permits early insemination..."); page 4, second full paragraph ("...gains are attributed to adjusted feed rations to allow for gains that would induce early puberty"); page 4, third full paragraph ("This induction of early puberty is contributed to nutrition allowing greater gain and weight of the EW heifers", "At time of PGF injection, the number of EW heifers cycling increased to 85% with only 7 heifers pre-pubertal"); page 5, second full paragraph ("...accomplished satisfactory gain performance of heifers which enabled induction of early puberty..."); page 8 ("...to induce early puberty by 9 mo of age", "... greater gains and weights of heifers induced early puberty").

Aspects relating to inseminating substantially all of the female bovine mammals with sex-sorted spermatozoa may be found, *inter alia*, at page 2, second full paragraph ("...AI using low dose sexed semen resulting in pregnancy rates..."); page 3, fourth full paragraph ("The IS produces all female progeny to perpetuate the system in subsequent years by utilizing sexed semen"); page 5, first full paragraph ("Heifers that became impregnated to sexed semen..."); page 5, second full paragraph ("...and resulted in 9 mo old heifers impregnated to sexed semen"), page 8 ("...resulted in 9 mo old heifers pregnant to sexed semen").

Aspects relating to producing offspring comprising substantially all female offspring may be found, *inter alia*, at page 2, second full paragraph ("Sexed semen is a relatively new technology that grants the IS ability to perpetuate the program using the female progeny of the initial heifers"); page 3, fourth full paragraph ("The IS produces all female progeny..."); page 8 ("Sexed semen can be utilized to yield female progeny, decrease calving difficulty risk and create a second generation to perpetuate the IS").

Aspects relating to harvesting substantially all of said plurality of female bovine mammals may be found, *inter alia*, at page 1, second full paragraph ("...a program designed to allow a heifer to produce one calf prior to harvest", "...in the SCH these animals are profitable because of faster growth during feedlot period and larger, more profitable carcasses", "...heifers to reach harvest weight by 30 months"); page 2, first full paragraph ("...produce a calf by 18 mo of age and a carcass by 24 mo of age", "... the period from weaning to harvest is shortened").

On page 3 of the Office Action, the Office asserts that Applicant's disclosure in the priority case that "Early puberty permits early insemination" does not provide support for various aspects of the claims. However, Applicant has not offered this disclosure as

providing support for all elements of the claims to which the Office attributes it. Rather, Applicant offered only that this disclosure supports Applicant's claimed recitation of "inducing early puberty in substantially all of said plurality of bovine female mammals". Moreover, the Office has failed to address the 8 other disclosures offered by Applicant on page 10 of the prior response (with corrected page and paragraph numbers as set forth in the second block paragraph, above), each of which also supports Applicant's claimed recitation of "inducing early puberty in substantially all of said plurality of bovine female mammals". Accordingly, the Applicant believes the Office has not demonstrated that the priority case does not support this claimed recitation.

On page 3 of the Office Action, the Office asserts that Applicant's disclosure in the priority case at page 4, 3<sup>rd</sup> full paragraph does not provide support for various aspects of the claims. Again, however, Applicant has not offered this disclosure as providing support for all elements of the claims to which the Office attributes it. Rather, Applicant offered only that this disclosure supports Applicant's claimed recitations of "managing said plurality of bovine female mammals for at least one reproductive factor" and "inducing early puberty in substantially all of said plurality of bovine female mammals". Moreover, the Office has failed to address the 21 other disclosures on page 9 of the prior response (with corrected page and paragraph numbers as set forth in the first block paragraph, above), each of which also supports Applicant's claimed recitation of "managing said plurality of bovine female mammals for at least one reproductive factor", and failed to address the 8 other disclosures offered by Applicant on page 10 of the prior response (with corrected page and paragraph numbers as set forth in the second block paragraph, above), each of which also supports Applicant's claimed recitation of "inducing early puberty in substantially all of said plurality of bovine female mammals". Accordingly, the Applicant believes the Office has not demonstrated that the priority case does not support these claimed recitations.

On page 3 of the Office Action, the Office asserts that Applicant's disclosure in the priority case that "Phase I of the integration of early weaning, sexed semen, and single-calf heifer systems achieved increased BCS of dams; accomplished satisfactory

gain performance of heifers which enabled induction of early puberty and resulted in 9 mo old heifers impregnated to sexed semen” and “Phase I of the IS increased BCS of dams, enabled greater gains and weights of heifers, induced early puberty and resulted in 9 mo old heifers pregnant to sexed semen” does not provide support for various aspects of the claims. Once more, however, Applicant has not offered this disclosure as providing support for all elements of the claims to which the Office attributes it. Rather, Applicant offered only that this disclosure supports Applicant’s claimed recitations of “managing said plurality of bovine female mammals for at least one reproductive factor”, “inducing early puberty in substantially all of said plurality of bovine female mammals” and “fertilizing at least one egg derived from each of said substantially all of said plurality of bovine female mammals, wherein fertilizing said at least one egg comprises fertilizing said at least one egg with a plurality of sex-sorted spermatozoa and prior to the typical age of puberty of said substantially all of said plurality of bovine female mammals”. Moreover, the Office has failed to address the 21 other disclosures on page 9 of the prior response (with corrected page and paragraph numbers as set forth in the first block paragraph, above), each of which also supports Applicant’s claimed recitation of “managing said plurality of bovine female mammals for at least one reproductive factor”, and failed to address the 8 other disclosures offered by Applicant on page 10 of the prior response (with corrected page and paragraph numbers as set forth in the second block paragraph, above), each of which also supports Applicant’s claimed recitation of “inducing early puberty in substantially all of said plurality of bovine female mammals”, and failed to address the 5 other disclosures offered by the Applicant on page 10 of the prior response (with corrected page and paragraph numbers as set forth in the third block paragraph, above), each of which also supports Applicant’s claimed recitation of “fertilizing at least one egg derived from each of said substantially all of said plurality of bovine female mammals, wherein fertilizing said at least one egg comprises fertilizing said at least one egg with a plurality of sex-sorted spermatozoa and prior to the typical age of puberty of said substantially all of said plurality of bovine female mammals”. Accordingly, the Applicant believes the Office has not demonstrated that the priority case does not support these claimed recitations.

In sum, Applicant in its prior response separately itemized each element of independent claim 28 and provided multiple bases of support for these elements in the priority case. The Office has not reviewed this support in relation to the claims elements for which Applicant offered them, nor considered all of the disclosure which Applicant provided. Accordingly, the Applicant respectfully requests the Office recognize Applicant's priority claims.

The Office maintains 35 USC § 112(2) concerns regarding certain recitations in the claims. On page 5 of the Office Action, the Office states that "Applicants do not point to any particular teaching in these references which define the phrase..." However, it appears to the Applicant that an express definition of a term within a reference is not required to establish its meaning. Rather, evidence that the term is customarily used by those skilled in the relevant art is sufficient. *See e.g.* MPEP § 2111.01 ("It is the use of the words in the context of the written description and *customarily by those skilled in the relevant art* that accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims" [emphasis added]). Here, Applicant has offered in the prior response multiple publications using the terms challenged by the Office as evidence that they are used customarily by those skilled in the relevant art. In particular, use of the term "managing for a reproductive factor" was shown in 5 separate peer-reviewed publications, having 13 different authors, and spanning a course of 8 years. Similarly, the term "unsexed spermatozoa" was shown in 6 different peer-reviewed publications, having 12 different authors, and spanning a course of 6 years. Accordingly, Applicant respectfully requests the Office acknowledge these terms have an ordinary and customary meaning, as evidenced by their use customarily by those skilled in the art, and withdraw the 35 USC § 112 (2) concern.

Additionally, the Applicant disagrees that the relationship between the term "managing for a reproductive factor" and the remaining steps of the claim is unclear. However, to facilitate examination of the case, Applicant has amended the claims to recite "managing said plurality of bovine female mammals for at least one artificial insemination reproductive factor". Because artificial insemination is not a natural event

and therefore necessarily requires human management of the factors governing it, Applicant believes clarity of relationship of the management recitation in step (b) to the artificial insemination recitations in the subsequent steps is enhanced.

Also, after reviewing the Office Action, Applicant is unclear as to whether the Office's 35 USC § 112(2) concern lies with the term "unsexed spermatozoa" or "a typical number of unsexed spermatozoa". If it is the former, then Applicant believes the meaning of this term is clear from its use customarily by those skilled in the art, as set forth above. If it is the latter, then Applicant believes the term is clearly defined in US 09/001,394, patented as US 6,149,867, incorporated by reference into the current case in the specification at page 10, lines 4-5. The '867 patent at column 12, lines 37-41 clearly states "For bovine sperm, where currently 1 to 10 million sperm are provided, a low dose process may be considered an absolute number of about 500,000 sperm or perhaps as low as 300,000 sperm or lower". From the context of the discussion in this patent at column 12, lines 27-49, where the term "currently 1 to 10 million sperm are provided" is contrasted with numbers that constitute a low dose, it is clear that the range of 1 to 10 million sperm is a typical number of unsexed spermatozoa.

The Office maintains obviousness concerns with respect to various combinations of references that rely on Ereth (Proceedings of the Western Section, 2000) and Ereth (Journal of Animal Science, 2000). As discussed above, Applicant believes the Office has not established that Applicant is not entitled to the benefit of its priority claims. Accordingly, Applicant believes the earliest priority date of the application (June 12, 2000) antedates the effective dates of the Ereth references (June 21, 2000) as established in Applicant's prior response. Accordingly, Applicant respectfully requests the Office withdraw its obviousness concerns.

Further with respect to the Ereth references, please find attached to this response as Exhibits "B" and "C" a first affidavit and a second affidavit under 37 C.F.R. § 1.132 from Barbi A. Riggs, an inventor on the current application. Applicant notes the Office on page 12 of the Office Action has raised a timeliness issue as outlined in MPEP §

716.01 with respect to the admission of an affidavit in this case. However, it appears to the Applicant that the version of the MPEP section quoted in the Office Action most recently appeared in MPEP Rev. 2, May 2004. In the currently effective MPEP, which is Rev. 6, Sept. 2007, § 716.01(A)(4) appears to permit affidavits under 37 C.F.R. § 1.132 with the filing of an RCE. Accordingly, Applicant believes the affidavits included herewith are timely filed. The first affidavit establishes that inventor Barbi A. Riggs on the current application is the same person as author B.A. Ereth on the Ereth references cited by the Office. The second affidavit establishes that the Ereth references cited by the Office describe the own work of the applicant on the present application, pursuant to MPEP § 716.10. Accordingly, Applicant submits the Ereth references must be disqualified, and respectfully requests the Office withdraw its obviousness concerns.

The Office maintains obviousness concerns with respect to various combinations of references that rely on Hohenboken in view of Petit and Hall. The Applicant disagrees that these combinations pose an obviousness issue with respect to the application. However, to facilitate examination of the case, Applicant has amended the claims to recite “inducing early puberty in substantially all of said plurality of bovine female mammals between about 250 days after birth to about 270 days after birth”. Applicant notes the Office on page 21 of the Office Action states “Hall teaches inducing early puberty by about 9.5 months of age (*i.e.* about 270 days after birth)”. However, Applicant respectfully disagrees with the Office’s calculation. Assuming a month has 30.5 days (by taking the average of a 30 day month and a 31 day month), 9.5 months in fact corresponds to approximately 290 days (9.5 months x 30.5 days/month = 289.75 days). This is nearly three weeks after the latest date of Applicant’s claimed range. Accordingly, the references cited by the Office do not teach all elements of the Applicant’s claims, and the Applicant respectfully requests the Office withdraw its obviousness concerns.

## CONCLUSION

Having addressed each of the concerns raised in the Office Action, the Applicant respectfully requests reconsideration and withdrawal of the rejections and objections to the application. Allowance of claims 28, 30-31, 33-40, 45-46, and 49-50 is requested at the Office's earliest convenience.

Dated this 31<sup>st</sup> day of October, 2007.

Respectfully submitted,  
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